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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/961,086	09/21/2001	Douglas D. Ross	028754-039	6592
<div>BURNS DOANE SWECKER & MATHIS L L P POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404</div>				
<div>EXAMINER UNGAR, SUSAN NMN</div>				
<div>ART UNIT PAPER NUMBER</div> <div>1642</div>				
DATE MAILED: 10/27/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/961,086

Applicant(s)

ROSS ET AL.

Examiner

Susan Ungar

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 11 February 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 5-7, 12-15, 18 and 21-39 is/are pending in the application.
- 4a) Of the above claim(s) 12-15, 18 and 21-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 5-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/26/02, 2/20/03

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

1. The Amendment filed August 10, 2004 in response to the Office Action mailed May 10, 2004 is acknowledged and has been entered. Previously pending claim 5 has been amended. Claim 5-7 are currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. It is noted that Applicant renews former traversal and requests rejoinder and examination of all the claims of record on the merits. The argument has been considered but has not been found persuasive and for the reasons of record the restriction requirement is maintained. However, it is noted for Applicant's information that if the claims should become allowable, Examiner will consider rejoining method claims that are found to be within the scope of the claimed invention. Further it is noted for Applicant's information that after a final requirement for restriction, the applicant, in addition to making any reply due on the remainder of the action, may petition the Director to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal.
4. The following rejections are maintained:

Claim Rejections - 35 USC §112

5. Claims 5-7 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed May 10, 2004, Section 8, pages 4-7.

Applicant argues that the amendment of claim 5 to recite "full length functional derivatives" overcomes the rejection and points Examiner to paragraphs 37-40 wherein a functional derivative is defined as a compound which possesses a biological activity, either functional or structural that is substantially similar to a

biological activity of BCRP and from the recitations in the specification one of ordinary skill would understand that the recitation of derivatives does not relate to a whole universe of molecules that would be expected to have neither structural nor functional identity with BCRP.

The argument have been considered but have not been found persuasive because the functions of BCRP have not been defined in any limiting manner. BCRP, like all proteins, functions as an antigen for the production of antibodies and although it is clear from the art rejections of record that other breast cancer resistance proteins also function as antigens, the same function is found in any expressed protein, thus the claims are still drawn to a whole universe of molecules that would be expected to have neither structural nor functional identity (other than their ability to serve as antigens) to the claimed invention. The argument has been considered but has not been found persuasive and the rejection is maintained.

6. Claims 5-7 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed May 10, 2004, Section 9, pages 7-10.

Applicant argues that (a) the claims are not drawn to DNA and since the claims are not drawn to DNA, the decisions in *Enzo* and *Lilly* are not relevant to the claimed invention (b) Applicant points to *In Noelle v. Lederman* wherein it was found that the application which described and claimed monoclonal antibody to a murine antigen did not adequately describe any kind of either human antigen or antigen from any mammal other than mouse and according to the Court, *Noelle* attempted to define an unknown by its binding affinity to another unknown. In contrast, the present claims are directed to antibodies to a protein with a defined sequence SEQ ID NO:1 and to full length functional derivatives thereof and as

discussed above the structure of those full-length functional derivatives is not unknown, rather it is clearly defined by reference to SEQ ID NO:1.

The arguments have been considered but have not been found persuasive because (a') the findings in *Enzo* and *Lilly* are relevant to the instant invention for the reasons of record, (b') contrary to Applicant's argument, the findings in *Noelle* are on point, the instant claims are drawn to an antibody that binds to a functional derivative with unknown structure, thus the instant claims are drawn to an antibody with unknown structure because of its binding affinity to a protein with an unknown structure. For the reasons set forth previously and above the full-length functional derivatives are not defined by reference to SEQ ID NO:1. The arguments have been considered but have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC §102

7. Claims 5-6 remain rejected under 35 USC 102(b), first paragraph for the reasons previously set forth in the paper mailed May 10, 2004, Section 12, pages 11-12.

Applicant argues that the antibodies of Filipits et al and Dexter et al are not directed to full-length functional derivatives of SEQ ID NO:1 as defined by the specification.

The arguments have been considered but have not been found persuasive because the specification defines a functional derivative as a compound which possesses a biological activity, either functional or structural, that is substantially similar to a biological activity of BCRP. For the reasons set forth above, the breast cancer resistance proteins of Filipits et al and Dexter et al clearly are functional derivatives of the instantly claimed SEQ ID NO:1 because they share the function

of breast cancer resistance. Further, although a “full length functional derivative” is neither disclosed nor defined in the specification, it is assumed for examination purposes that full length functional derivatives are derivatives that consist of a full length protein and since the breast cancer resistance proteins of Filipits et al and Dexter et al are full length proteins, the prior art reference meets all of the limitations of the claims. The argument has been considered but has not been found persuasive and the rejection is maintained.

8. Claims 5 and 7 remain rejected under 35 USC 102(b), first paragraph for the reasons previously set forth in the paper mailed May 10, 2004, Section 13, pages 12-13.

Applicant reiterates arguments drawn to the rejection of claims 5-6 over Filipits et al and Dexter et al as set forth above, but draws the arguments to the Nakagawa et al reference. The arguments have been considered but have not been found persuasive and for the reasons set forth above, drawn to the Filipits et al and Dexter et al references, the rejection is maintained.

Claim Rejections - 35 USC § 103

9. Claims 5 and 7 remain rejected under 35 USC 103 for the reasons previously set forth in the paper mailed May 10, 2004, Section 15, pages 14-16.

Applicant reiterates arguments drawn to the rejection of claims 5-6 over Filipits et al and Dexter et al as set forth above. Applicant further argues that although Harlow et al teach methods of making polyclonal antibodies, this does not remedy the deficiencies of the Filipits et al and Dexter et al references. The arguments have been considered and for the reasons set forth previously and above, the rejection of claims 5-6 over Filipits et al and Dexter et al are maintained and the teachings of Harlow et al make obvious the claimed invention for the

reasons of record. The arguments have been considered but have not been found persuasive and the rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

10. Claims 5-7 are rejected under 35 USC 112, first paragraph because neither the specification nor the claims as originally filed provide support for the newly added limitation in Claim 5 drawn to “full length functional derivative”. Although Applicant specifically states, on page 14 of the Response to the first action on the merits, that “As defined in the specification, full length functional derivatives share both structural and functional characteristics with BCRP”, a review of the specification did not reveal this teaching. Instead a review of the specification did not reveal a single reference to a “full length functional derivative” but did reveal that a functional derivative is a compound which possesses a biological activity (either functional or structural) that is substantially similar to a biological activity of BCRP. It is further noted that, as previously set forth, the indefinite term “substantially” is not defined by the specification. The newly added limitation alters the scope of the invention, claims 5-7 as originally filed.

11. All other objections and rejections recited imposed in the paper mailed May 10, 2004 are hereby withdrawn.

12. No claims allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R., 1.136(a).

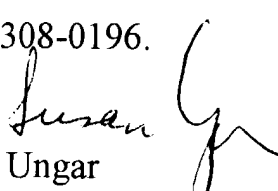
A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF

THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Susan Ungar
Primary Patent Examiner
October 12, 2004